

## **REMARKS**

### **1. The Restriction Requirement**

The Examiner alleges that the application contains three inventions which are not so linked as to form a single general inventive concept under PCT rule 13.1. The Examiner has defined the inventions as follows:

**Invention 1**, claims 1-5, drawn to a fructosylamine oxidase.

**Invention 2**, claims 6-10, drawn to a DNA encoding a fructosylamine oxidase, host cell and method for preparing a fructosylamine oxidase.

**Invention 3**, claim 11, drawn to a method of measuring amadori compound in a sample;

The Examiner contends that Inventions 1-3 do not relate to a single general inventive concept under PCT rule 13.1 because, under PCT rule 13.2, the technical feature shared by the claims is not novel over the prior art. Here, the Examiner contends that the common technical feature of the claims is "a fructosylamine oxidase of any sequence and structure." The Examiner then states that a fructosylamine oxidase disclosed by Accession AAW69251 (1998) has 92.4% amino acid identity to that of the presently claimed fructosylamine oxidase. Based on these points, the Examiner finds that Accession AAW69251 anticipates the fructosylamine oxidase of the invention, so the common technical feature is not special under PCT Rule 13.2, and the claims of the application lack unity of invention under PCT Rule 13.1. (Office Action, page 2). Applicants respectfully traverse.

It is well established that anticipation requires that each element of the claim at issue is found in a single prior art reference, either expressly or inherently. Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983). Moreover, anticipation by inherent disclosure is appropriate only when the reference discloses prior art that must necessarily include the unstated limitation, [or

the reference] cannot inherently anticipate the claims. Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364, 1373 (Fed. Cir. 2002). That a feature in the prior art reference “could” operate as claimed does not establish inherency; nor is it sufficient if a material [claim] element or limitation is “merely probably or possibly present” in the prior art. In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) and Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295 (Fed. Cir. 2002).

With these standards in mind, Applicants point out that, in finding the present claims anticipated by the amino acid sequence disclosed by Accession AAW69251, the Examiner failed to take into consideration any and all claim limitations other than the amino acid sequence of the presently claimed fructosylamine oxidase. The limitations ignored by the Examiner include enzymatic activity, optimum pH, optimum temperature and SDS PAGE weight limitations. Applicants point out that the prior art Accession AAW69251 reference fails to teach any of these properties for its amino acid sequence.

Although the Examiner alleges that the amino acid sequence taught by Accession AAW69251 to have fructosyl oxidase activity, the Examiner does not support this allegation with scientific publications or any other evidence. Moreover, the Examiner completely fails to allege the amino acid sequence taught by Accession AAW69251 has any of the other properties specified by the present claims. Accordingly, under Kalman v. Kimberly-Clark Corp., Accession AAW69251 is not an anticipating reference.

Applicants also submit that a person of skill in the art would recognize that presently claimed properties such as enzymatic activity, optimum pH, optimum temperature and SDS PAGE migration weight are not necessarily the same between amino acid sequences sharing 92.4% sequence identity. As discussed above, simply because a feature in a prior art reference “could” operate as claimed does not establish inherency; nor is it sufficient if a claim element or limitation is “merely probably or possibly present” in the prior art. It follows that, under

Transclean Corp. v. Bridgewood Servs., Inc., In re Robertson, and Trintec Indus., Inc. v. Top-U.S.A. Corp., Accession AAW69251 is not an inherently anticipating reference.

Since the amino acid sequence taught by Accession AAW69251 does not, either expressly or inherently, anticipate the presently claimed fructosylaminase, the common technical feature cited by the Examiner in imposing the restriction requirement is indeed special under PCT Rule 13.2. Unity of Invention therefore exists under PCT Rule 13.1, and the restriction requirement is improper. Applicants respectfully request its withdrawal and rejoinder of all pending claims for examination in a single application.

In order to be fully compliant with the Restriction Requirement, Applicants elect, with traverse, the claims of Invention 1. Applicants also reserve their right to rejoinder of the method claims in the present application upon the finding of patentability regarding the claims drawn to the fructosyl oxidase of the invention.

## **2. Conclusion**

Applicants respectfully request early action on this application and allowance of all the claims, which define patentable subject matter.

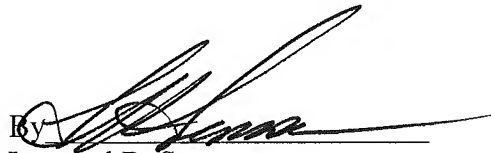
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson, Registration No. 33,330, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Application No.: 10/528,992  
May 21, 2007

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,



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